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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/588,051	03/07/2007	Thomas Tallberg	U 016420-2	4058

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EXAMINER	
HUANG, GIGI GEORGIANA	
ART UNIT	PAPER NUMBER
1612	
MAIL DATE	DELIVERY MODE
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/588,051	TALLBERG, THOMAS	
	Examiner	Art Unit	
	GIGI HUANG	1612	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *15 July 2008*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *2-7,10 and 11* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *2-7, 10 and 11* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Status of Application

1. The response filed July 15, 2008 has been received, entered and carefully considered. The response affects the instant application accordingly:

   a. Claims 3 and 10 have been amended.

   b. Claim 8-9 has been cancelled.

   c. Claim 11 has been added.

2. Claims 2-7 and 10-11 are pending in the case.

3. Claims 2-7 and 10-11 are present for examination.

4. The text of those sections of title 35.U.S. Code not included in this action can be found in the prior Office action.

5. All grounds not addressed in the action are withdrawn.

6. New grounds of rejection are set forth in the current office action.

New Grounds of Rejection

7. Due to the amendment of the claims the new grounds of rejection are applied:

Claim Rejections - 35 USC § 112

8. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

9. Claim 11 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled

in the relevant art that the inventor, at the time the application was filed, had possession of the claimed invention.

The claim is drawn to a method of preventing an outbreak of psoriasis comprising oral administration of pharmaceutically active amounts of L-serine and L-isoleucine, chromium, tin, selenium, vanadium, wolfram (tungsten), and folic acid. There is no support in the specification for this method. Applicant cites support on Page 3 lines 2-5 in the specification. The area of the specification cited states that close family members of the cancer patients suffered from bouts of psoriasis but were otherwise healthy, could ingest the same natural dietary components which "could cause a favorable clinical effect". The statement is a hypothetical as to what the effect of the composition on healthy subjects and the term "could cause a favorable clinical effect" does not lend support to a "method of preventing an outbreak of psoriasis" as there is no statement to support this specific method, no testing or comparative done to support a description as to what is a "favorable clinical effect" with respect to "method of preventing an outbreak of psoriasis". It can be a reduction in the size of the plaque, the duration of psoriasis, a modification of the symptoms, a change in sensation, for example.

The examples presented in Page 5-6 are for treatment of the condition as it showed less irritation and some resolution of the psoriasis that was present. There is no support, description, or clear statement for a "method of preventing an outbreak of psoriasis", only for the prevention of psoriasis and the treatment of psoriasis which was subject to a scope of an enablement rejection addressed in the previous action.

10. Claim 11 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The specification is not enabled for a method of preventing an outbreak of psoriasis comprising oral administration of pharmaceutically active amounts of L-serine and L-isoleucine, chromium, tin, selenium, vanadium, wolfram (tungsten), and folic acid as claimed.

The factors to be considered in determining whether a disclosure meets the enablement requirements of 35 U.S.C. 112, first paragraph, have been described in *In re Wands*, 858 F.2d 731, 8 USPQ2d 1400 (Fed. Cir., 1988). The court in Wands states, "Enablement is not precluded by the necessity for some experimentation, such as routine screening. However, experimentation needed to practice the invention must not be undue experimentation. The key word is 'undue', not 'experimentation'" (*Wands*, 8 USPQ2sd 1404). Clearly, enablement of a claimed invention cannot be predicated on the basis of quantity of experimentation required to make or use the invention. "Whether undue experimentation is needed is not a single, simple factual determination, but rather is a conclusion reached by weighing many factual considerations" (*Wands*, 8 USPQ2d 1404). Among these factors are: (1) the nature of the invention; (2) the breadth of the claims; (3) the state of the prior art; (4) the predictability or unpredictability of the art; (5) the relative skill of those in the art; (6) the amount of

direction or guidance presented; (7) the presence or absence of working examples; and (8) the quantity of experimentation necessary.

While all of these factors are considered, a sufficient amount for a *prima facie* case is discussed below.

(1) The nature of the invention and (2) the breadth of the claims:

The claims are drawn to the method of preventing an outbreak of psoriasis comprising oral administration of pharmaceutically active amounts of L-serine and L-isoleucine, chromium, tin, selenium, vanadium, wolfram (tungsten), and folic acid. Thus, the claims taken together with the specification imply that the composition is able to prevent an outbreak of psoriasis.

(3) The state of the prior art and (4) the predictability or unpredictability of the art:

The state of the art does not recognize psoriasis as curative, and the art states that the cause is unknown (see Merck Manual sheets). As a result, if the mechanism is not known- an outbreak cannot be prevented since it is not possible to affect the cascade when the mechanism is not known. There are common triggers and several modalities of treatment but no methods of prevention. The high degree of unpredictability in the treatment of skin diseases is well known in the art. The specification does not provide any competent evidence or disclosed tests that are highly predictive for the pharmaceutical use as claimed of the instant composition. This also goes to the issue of written description addressed above.

(5) The relative skill of those in the art:

The relative skill of those in the art is high.

(6) The amount of direction or guidance presented and (7) the presence or absence of working examples:

The specification does not provide for any disclosure or working examples for a method of preventing an outbreak of psoriasis comprising oral administration of pharmaceutically active amounts of L-serine and L-isoleucine, chromium, tin, selenium, vanadium, wolfram (tungsten), and folic acid. This goes to the issue of written description addressed above.

(8) The quantity of experimentation necessary:

Considering the state of the art as discussed by the references above, particularly with regards to the unknown etiology of psoriasis and the high unpredictability in the art as evidenced therein, and the lack of guidance provided in the specification, one of ordinary skill in the art would be burdened with undue experimentation to practice the invention commensurate in the scope of the claims.

11. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

12. Claims 10-11 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The claim is unclear as to if it is to the administration of a composition or other forms. For purposes of prosecution, it is viewed as a composition.

13. Claims 2-7 rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 2-7 recites the limitation "pharmaceutical composition" in claim 10. There is insufficient antecedent basis for this limitation in the claim.

Claim Rejections - 35 USC § 103

14. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

15. Claims 3-7 and 10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Tallberg et al. (Studies on Mitochondrial Regulation of the Genome), in view of Bodaness (U.S. Pat. No. 5563132).

Tallberg et al. teaches compositions comprising amino acids and trace elements for bio-immunotherapy. specific components fed to a patient suffering from skin tumors (e.g. fibrotic histiocytoma, Merkel sarcoma, melanoma) comprised of isoleucine, serine, chromium, selenium, tin, vanadium, wolfram, manganese, folic acid, pig brain (neurogenic lipid), and multivitamins (see Page 134).

Additionally, Tallberg teaches the use of these compositions comprising of isoleucine, serine, chromium, selenium, tin, vanadium, wolfram, manganese, folic acid, pig brain (neurogenic lipid), and multivitamins orally for active immunotherapy to

regress, heal, or transform the tumor into normal skin tissue. The trace elements are also presented in salt form.

Tallberg et al. does not expressly teach the use of these compositions for psoriasis.

Bodaness teaches the use of a composition comprising metal ion complexes wherein several of the metal ions for the complexes are those in the instant invention (e.g. vanadium, chromium, manganese, tin, and tungsten/wolfram). The compositions were used for the treatment of skin conditions including skin cancers, premalignant lesions, and psoriasis. They can be administered in many forms including orally, topically, intralesionally, intravenously (Col.4, lines 39-48, Col.7, lines 33-40, Col. 11 lines 44-55, Col.15, lines 26-36, Col. 16, line 3).

It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to utilize the compositions for psoriasis, as suggested by Bodaness, and produce the instant invention. It would have been obvious to utilize the composition for psoriasis as it is common in the art to utilize compositions that are useful for skin cancer/tumors for psoriasis as evidenced by Bodaness particularly as several of the metals/elements are common to both compositions.

One of ordinary skill in the art would have been motivated to do this because it is desirable to utilize a composition for other conditions when there is a suggestion in the art to use materials for skin cancer and psoriasis.

A reference is good not only for what it teaches by direct anticipation but also for what one of ordinary skill in the art might reasonably infer from the teachings. From the teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole was *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

16. Claim 2 is rejected under 35 U.S.C. 103(a) as being unpatentable over Tallberg et al. (Studies on Mitochondrial Regulation of the Genome), in view of Bodaness (U.S. Pat. No. 5563132, as applied to claims 3-7 and 10 above, and further in view of Yoneda et al. (U.S. Pat. No. 5997852).

The teachings of Tallberg et al. in view of Bodaness are addressed above.

Tallberg et al. in view of Bodaness does not expressly teach the incorporation of zinc.

Yoneda et al. teaches the administration of zinc (i.e. oral) for treating several conditions including psoriasis. Yoneda also teaches that psoriasis is linked to zinc deficiency and the composition can include other components such as minerals, vitamins, and amino acids (Abstract, Col. 1 line 1-28, Col. 2 line 10-35, 50-58, Col. 3 line 10-25).

It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to include zinc in a composition for psoriasis, as suggested by Yoneda, and produce the instant invention. It would have been obvious to combine

two compositions (Tallberg and Bodaness composition and zinc by Yoneda) each of which is taught by prior art to be useful for same purpose in order to form third composition that is to be used for very same purpose; the idea of combining them flows logically from their having been individually taught in prior art.

One of ordinary skill in the art would have been motivated to do this because it is desirable to have improved and additive effects for treating a condition.

A reference is good not only for what it teaches by direct anticipation but also for what one of ordinary skill in the art might reasonably infer from the teachings. From the teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole was *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

Response to Arguments

17. Claim 5 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement is regards to the term "neurogenic lipids".

Applicant's arguments filed 7/15/2008 have been fully considered but they are not persuasive. Applicant asserts that the term is understood by one of the art to be one that was extracted from the nervous system. This is not persuasive as the specification does not provide a written description of what are neurogenic lipids. The term attempts to describe the lipids by what they *do* (as it does to any lipid with neurogenic properties)

or where they *can be from* (whereby other lipids could have same structure, but be from other things), but not what they *are*.

This is further complicated by the fact that the specification states the neurogenic lipids are purchased and canned by Neurofood Ltd. Whereby there is no disclosure as to what are the specific components or lipids are used and as the "neurogenic lipids" are purchased from a commercial source with no disclosure of which specific product what purchased and utilized, whereby it does not allow one of skill in the art to ascertain what the material is. Second if the commercial product is trademarked, the identification/description does not provide adequate written description as it is indefinite. Where a trademark or trade name is used to identify or describe a particular material or product, the material becomes uncertain since the trademark or trade name cannot be used properly to identify any particular material or product. A trademark or trade name is used to identify a source of goods, and not the goods themselves. Thus, a trademark or trade name does not identify or describe the goods associated with the trademark or trade name.

Accordingly, the rejection is maintained.

18. Applicant's arguments with respect to claims 2-7 and 10 rejected under 35 U.S.C. 103(a) as being unpatentable over Tallberg et al. (Studies on Mitochondrial Regulation of the Genome), as applied in claim 8 above, in view of Bodaness (U.S. Pat. No. 5563132), and further in view of Dong et al. (CN 1372926) have been considered but are moot in view of the new grounds of rejection.

Conclusion

19. Claims 2-7 and 10-11 are rejected.

20. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to GIGI HUANG whose telephone number is (571)272-9073. The examiner can normally be reached on Monday-Thursday 8:30AM-6:00PM EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Fredrick Krass can be reached on 571-272-0580. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

GH
/Zohreh A Fay/
Primary Examiner, Art Unit 1612